

Docket Number EPA-HQ-OPP-2009-0113

**Garlic oil
Final Registration Review Decision
Case 4007**

Garlic oil – PC Code 128827

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I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) Final *Registration Review Decision* for *Garlic oil* and is being issued in accordance with 40 CFR §§ 155.57 and 155.58. A registration review decision is the Agency's determination whether a pesticide meets, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). For further information on *Garlic oil*, additional documents can be found in EPA's public docket (EPA-HQ-OPP-2009-0113) at www.regulations.gov.

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, mandated the continuous review of existing pesticides. All pesticides distributed or sold in the United States must generally be registered by EPA, based on scientific data showing that they will not cause unreasonable risks to human health or the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health or the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can be used safely. Information on this program is provided at: http://www.epa.gov/oppsrrd1/registration_review/.

In 2006, the Agency implemented the Registration Review program pursuant to FIFRA section 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

In accordance with 40 CFR § 155.50, the Agency formally initiated registration review for *Garlic oil* (Case 4007). The following timeline highlights significant events that have occurred during the registration review of *Garlic oil*:

- March 25, 2009 – Issuance of the *Garlic oil Summary Document* in the docket (EPA-HQ-OPP-2009-0113) for a 60-day public comment period. The *Summary Document* also included the preliminary work plan (PWP). No comments were received.
- October 6, 2009 – Issuance of the *Garlic oil Final Work Plan*, which stated that the most recent exposure and risk assessments still supported the registration of the currently registered pesticide products containing *Garlic oil* and that these products appeared to have met the requirement of registration review under 40 CFR § 155.50.
- April 2010 – Publication of the *Garlic Oil Registration Review Proposed Final Decision* for a 60-day public comment period. No comments were received. The document proposed a final registration review decision affirming that the data on file continue to adequately support the registered pesticides containing Garlic Oil.
- September 2010 - Publication of the *Garlic Oil Registration Review Decision*, which formally determined that registered pesticides containing Garlic Oil met the current standards of registration under FIFRA.

The data and information evaluated to support *Garlic oil*, as published in the *Summary Document* (March 25, 2009), continue to support the pesticide registration as summarized herein. The status of this and other registration review cases is available at: http://www.epa.gov/oppsrrd1/registration_review/. Additional information on *Garlic oil* is available on the Biopesticides and Pollution Prevention Division's website in the form of succinct fact sheets (<http://www.epa.gov/oppbppd1/biopesticides/ingredients/index.htm>). The Agency plans to publish a more comprehensive Biopesticides Registration Action Documents (BRAD) for *Garlic oil*. That document will publish on the same website.

On October 26, 2007, the Agency issued a Final Rule in the Federal Register (FR) on the data requirements to support registration of biochemical and microbial pesticides and updated definitions for both biochemical and microbial pesticides (72 FR 61002). This rule became effective on December 26, 2007. The data and information summarized below were considered in light of these requirements.

A. General Background

Garlic oil is a derivative of a ubiquitously grown plant called *Allium sativum* which is commonly known as Garlic. Garlic products are grown and consumed globally and have been part of the human diet for hundreds of years. Garlic is considered to be a vegetable and the Garlic plant is a species in the lily and onion family and is a member of the same plant family as shallots, leeks, and chives. As a food item, Garlic is listed as generally recognized as safe (GRAS) by the Food and Drug Administration (21 CFR 182.20). Garlic oil for pesticidal use is formulated as a powder or a distilled extract which is formed when the essential oil from garlic cloves is combined with either oil or water. (See Table 1 of the Appendix to this document for detailed information on the chemical identity of Garlic oil). As a biochemical pesticide, Garlic oil is used mainly as an insect and animal repellent. The EPA first registered a product containing Garlic oil in 1983. Garlic oil is currently registered as an active ingredient in 11 products. The labels for these products interchangeably list the active ingredient as Garlic oil, Garlic Juice, Garlic Water, or Garlic. All products are water-based compounds with extract of *Allium sativum* or powder. The EPA considers all such variations of *Allium sativum* to be Garlic oil and all are grouped under the PC Code 128827 and CAS Registry Number 8000-78-0. Garlic oil is also listed as minimum risk pesticide by EPA in 40 CFR 152.25(f) (1), and as such, a product containing it may be exempt from the requirements of FIFRA when all of the conditions contained in 40 CFR 152.25(f) are met. Use patterns for Garlic oil include terrestrial, and greenhouse food, feed, and nonfood crops, and residential uses. Garlic oil pesticide products are applied aerially or by ground equipment, and are registered for use to repel birds, insects, deer and rabbits and thus prevent them from damaging seeds and seedlings of vegetable plants, fruit trees, grain crops, ornamental plants, and shrubbery. Garlic oil is not considered toxic or pathogenic to humans, animals, or plants (U.S. EPA 1992).

B. Garlic oil Registered Pesticide Products

Garlic oil is an active ingredient in 11 products (10 end-use products, 1 manufacturing-use product) registered with the Agency. Principle registrants of Garlic oil products are Helena

Chemical Co., Kitten Moseley Fertilizer & Supply, Inc., Balk Family Trust, and Woodstream Corporation. Table 3 of the Appendix to this document provides registration information for each of the 11 registered products.

II. SCIENTIFIC ASSESSMENT

A. Product Analysis (40 CFR § 158.2120)

The body of public literature on Garlic oil is comprehensive and provides sufficient information to support the Agency's generic product chemistry data requirements for Garlic oil. The Agency would normally require a complete data set on the technical grade active ingredient (TGAI) per the guidelines at 40 CFR 158.2030. However, the FDA and the EPA have determined that there is a reasonable certainty that there will be no harm to the general population from exposure to garlic (21 CFR 582.10 and 21 CFR 582.20, and 40 CFR 180.950). Since garlic is a commonly consumed food item, the Agency continues to waive some product chemistry data requirements, on a case-by-case basis, on the technical grade active ingredient (40CFR 158.2030). (References to these generic sources of public literature can be found in the Bibliography of this document.) In addition to single active ingredient products, the biochemical active ingredient Garlic oil is often formulated with other pesticides and therefore extensive information is available on end use products containing it.

Each of the currently registered products containing Garlic oil rely on different data to fulfill specific data requirements. The data and information submitted to support applications for registration for the active ingredient Garlic oil were reassessed and found sufficient to fulfill current product chemistry data requirements (40 CFR § 158.2030) for all use patterns described above. Adequate product analysis data for Garlic oil is contained in the June, 1992, Reregistration Eligibility Document (RED), and the May 1995, Risk Assessment relative to pesticide tolerances for the bulb vegetables Crop Grouping (40 CFR 180.41). These data and information are further supported by the reassessment documents and information associated with this registration review. These reassessment documents are included in the docket for this action (EPA-HQ-OPP-2009-0113) and referenced in the Bibliography to this document. A summary of the specific physical and chemical characteristics of Garlic oil is found in Table 1 of the Appendix to this document. A summary of the Agency's specific product chemistry data requirements is listed in Table 2, and a list of supporting product chemistry studies (including MRIDs) can be found within the List of Studies Submitted to Support Registration of Products Containing Garlic oil in the references section of this document.

B. Human Health

1. Acute Toxicity – Tier I (40 CFR § 158.2050)

Hazard and exposure information as well as Agency risk assessments on Garlic oil were evaluated against current safety standards established by statute, regulation and the Agency's scientific policies and it was determined that there is no need to conduct an additional human

health risk assessment. Garlic is a naturally-occurring substance, has a non-toxic mode of action (it is a repellent) and there is a significant history of exposure to humans and the environment. According to the Agency's Incident Data System, there have been no reports of incidents from use of products containing Garlic oil as an active ingredient. The human hazard and exposure assessments for Garlic Oil indicate that the risks to human health are negligible to non-existent when products containing Garlic Oil are used according to the label instructions. These assessments are considered complete and current and satisfy the standards for registration review.

Although data on the technical grade of active ingredients (TGAI) are required under 40 CFR 158.2050, because Garlic oil is considered a minimum risk pesticide; is a commonly consumed food commodity; and has a significant history of exposure to humans, the Agency has historically waived toxicology data on Garlic oil. Based on the available information on Garlic oil and its current uses as a pesticide, the Agency expects to continue to waive generic toxicology data requirements for the TGAI. However, toxicology data requirements must be fulfilled for manufacturing products (MPs) and end-use products (EPs) containing Garlic oil. The Agency has on file toxicology data and information that satisfy these requirements for all currently registered EPs. These data and information indicate that these products are of low toxicity.

If all of the conditions in 40 CFR 152.25(f) were met, Garlic oil would be considered to be a minimum risk pesticide for a given product and a qualifying product containing it would be exempt from certain requirements of FIFRA. Under 21 CFR 182.10 (spices and other natural seasonings and flavorings) and 21 CFR 182.20 (essential oils, oleoresins [solvent-free] and natural extractives [including distillates] as affirmed in 184.1317 [Garlic and its derivatives]), Garlic is classified as generally recognized as safe (GRAS). Garlic (*Allium sativum*) is broadly available in the United States for human consumption and is valued for its benefits to human health. Based on its composition and physical and chemical properties, as explained later, Garlic is considered to be non-persistent in the environment. It degrades rapidly in the environment and therefore, human exposure to pesticidal residues is expected to be minimal.

2. FQPA Assessment: Dietary Exposure and Risk Characterization

Section 408(c)(2)(A)(i) of the Federal Food, Drug, and Cosmetic Act (FFDCA) allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in

establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Additionally, section 408(b)(2)(D) of FFDCA requires that the Agency consider “available information concerning the cumulative effects of a particular pesticide's residues” and “other substances that have a common mechanism of toxicity.”

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information, and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

On the basis of data and information in the Agency's database and information and data submitted to support product registrations the Agency has determined that the data requirements required for FQPA risk assessments for *Garlic oil* have been satisfied.

a. Aggregate Exposures

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

i Dietary Exposure and Risk Characterization

The use of Garlic oil as a biochemical pesticide is not expected to result in any new dietary exposure to adults, infants, and children because Garlic oil has a non toxic mode of action and is considered a commonly consumed food commodity. In addition, standard practices of washing, peeling, cooking, or processing fruits and vegetables reduces residues of Garlic oil and further minimizes dietary exposure. Because of its ubiquitous presence in the environment, the Agency expects there to be no increase in exposure to Garlic oil resulting from the existing pesticidal uses when compared to existing exposure to background levels of Garlic oil.

Dietary risk is minimal due to the demonstrated lack of acute oral toxicity associated with Garlic oil. Based on evaluation of the associated toxicity data, there are no dietary risks that exceed the Agency's level of concern as noted in the Agency's Food Tolerance Exemption for Garlic oil (60 FR 26627, 67 FR 36537 and 72 FR 69150).

ii. Drinking Water Risk Characterization

Exposure to humans from residues of Garlic oil in consumed drinking water would be unlikely. The existing use sites of Garlic oil do not include direct application to aquatic environments. Potential exposure to surface water would be negligible. The risk of this biochemical passing through the soil to ground water is minimal to unlikely. If oral exposure should occur through drinking water, the Agency concludes that such exposure would present insignificant risk due to the lack of acute oral toxicity/pathogenicity and the ubiquitous nature of garlic.

iii. Non-Occupational, Residential Risk Characterization

The use sites for products containing Garlic oil include both agricultural and residential sites. Non-occupational exposures are expected to be minimal. The residential uses of Garlic oil are characterized by direct applications which are generally limited to outdoor use. Based on evaluations of the Tier I acute toxicity data and information, the Agency believes that the potential aggregate non-occupational risk derived from dermal and inhalation exposure, through the application of Garlic oil will be minimal. (60 FR 26627, 67 FR 36537 and 72 FR 69150).

b. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effects of exposure to Garlic oil and to other substances that have a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children.

No mechanism of toxicity in mammals has been identified for Garlic oil. Therefore, no cumulative effect with other related substances is anticipated. Because the data available demonstrate a low toxicity potential for Garlic oil, the likelihood of adverse dietary effects is expected to be minimal.

c. Determination of Safety for U.S. Population, Infants, and Children

FFDCA section 408(b)(2)(C) provides that EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) also provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of exposure (safety), which are often referred to as uncertainty factors, are incorporated into EPA risk assessment either directly or through the use of a margin of exposure analysis, or by using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk.

Based on the available acute data for Garlic oil, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to the United States population, including infants and children, to the residues of Garlic oil. This includes all anticipated dietary

exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because the submitted data available on the Garlic oil do not appear to demonstrate toxic potential to mammals. Thus, there are no threshold effects of concern and, as a result, the provision requiring an additional margin of safety does not apply. Further, the considerations of consumption patterns, special susceptibility, and cumulative effects do not apply to pesticides without a demonstrated significant adverse effect.

d. Food Tolerance Exemptions

On July 1, 2003, the Agency established an exemption from the requirement of a tolerance for residues of the biochemical pesticide Garlic oil when used in or on all food commodities when used in accordance with approved label rates and good agricultural practices (40 CFR § 180.950; 68 FR 18552).

4. Occupational Exposure and Risk Characterization

In light of the Tier I acute toxicity/ studies conducted with Garlic oil, which did not show any toxic effects to rats via oral, pulmonary, dermal, and intravenous routes of exposure, occupational exposure to Garlic oil is not expected to pose any undue risk. Regardless, appropriate personal protective equipment and precautionary statements are required on the product labels to mitigate any potential risks to pesticide handlers due to prolonged exposure.

5. Endocrine Disruptors

As required under FFDCA section 408(p), EPA has developed the Endocrine Disruptor Screening Program (EDSP) to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine related effects caused by the substance, and establish a quantitative relationship between the dose and the E, A, or T effect.

Between October 2009, and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. This list of chemicals was selected based on the potential for human exposure through pathways such as food and water, residential activity, and certain post-application agricultural scenarios. This list should not be construed as a list of known or likely endocrine disruptors.

Garlic oil is not among the group of 58 pesticide active ingredients on the initial list to be screened under the EDSP. Under FFDCA § 408(p) the Agency must screen all pesticide chemicals. Accordingly, EPA anticipates issuing future EDSP orders/data call-ins for all Registration Review cases, including those for which EPA has already opened a Registration Review docket for a pesticide active ingredient.

For further information on the status of the EDSP, the policies and procedures, the list of 67 chemicals, the test guidelines and the Tier 1 screening battery, please visit our website: <http://www.epa.gov/endo/>.

6.. Human Health Risk Characterization

The human hazard and exposure assessments for Garlic oil indicate that the risks to human health are negligible to non-existent when products containing Garlic oil are used in accordance with their labels. These assessments are considered complete and current, and satisfy the standards of registration review. All biochemical pesticide toxicology data requirements, applicable to human health effects determinations for Garlic oil, were considered and are fulfilled. Human health hazard and exposure scientific reviews for Garlic oil are located in the Garlic oil registration review docket (EPA-HQ-OPP-2009-0113).

C. Environmental Assessment

Based on the available information for Garlic oil, the Agency does not foresee the need for additional ecotoxicity data for a new risk assessment for this registration review. EPA has waived all hazard and exposure data on this chemical. The unique characteristics of this chemical, its non-toxic mode of action, and biodegradability (low to no persistence) should minimize the risks to all non-targets, including threatened and endangered species.

1. Effects on Non-Target Organisms – Tier I (40 CFR § 158.2060)

All Tier I ecotoxicity data requirements for Garlic oil have been waived. The existing waiver rationales on file with the Agency, and presented in the 1992 RED, have been reassessed in the course of registration review and are considered sufficient to fulfill current ecotoxicity data requirements. Garlic oil is non-toxic and acts only as a repellent and it biodegrades rapidly. As a result, there is minimal potential exposure to either aquatic or terrestrial species and what exposure may occur would not result in any toxic effect. Specific information on mammalian toxicology affirms that garlic oil is non-toxic to mammals through acute inhalation, dermal and dietary routes of exposure and strongly indicate that Garlic oil should be nontoxic to all terrestrial wildlife.

2. Environmental Fate, Ecological Exposure, and Environmental Expression – Tiers II, III, and IV (40 CFR § 158.2150)

Environmental fate data requirements (i.e., Tiers II, III, and IV) were not triggered for any of the registered garlic oil products. Tier I studies did not demonstrate adverse hazards and the Agency expects any risks to endangered species to be minimal.

3. Endangered Species Assessment

Based on the available data, the non-toxic mode of action of Garlic oil, and Garlic oil's ability to biodegrade rapidly, EPA has determined that registered uses of garlic oil will have "No Effect" on endangered and threatened terrestrial or aquatic species, or any designated critical habitat, as listed by the United States Fish and Wildlife Service and the National Marine Fisheries Service. The 'Garlic Oil Endangered Species Assessment' and the results of the Individual Effects Model can be found in the Registration Review docket EPA-HQ-2009-0113.

4. Environmental Risk Characterization

Based on the reviews of the aforementioned non-target organism and environmental fate studies, and the endangered species assessment, the Agency has determined that unreasonable adverse effects to non-target organisms or the environment are not likely to result when products containing Garlic oil are used in accordance with their labels. These assessments are considered complete and current, and satisfy the standards of registration review.

D. Product Performance (Efficacy) (40 CFR § 158.2170)

Product performance data must be developed for all biochemical pesticides to ensure efficacy when used in accordance with labeling directions and commonly accepted pest control practices. The Agency has waived all requirements to submit such efficacy data unless the pesticide product bears a claim to control public health pests, although the Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration. Registered Garlic oil pesticide products do not have labeled uses for public health pests.

E. Incidents

According to the Agency's Incident Data System, there have been no reports of adverse human health or environmental incidents in association with Garlic oil.

F. Public Comments

In accordance with 40 CFR § 155.50, the Agency formally initiated registration review for Garlic oil on March 25, 2009 with the opening of a docket and the issuance of a Summary Document for a 60-day public comment period. The Agency received no comments in response to the Garlic oil Summary Document and the initial opening of the docket. The Garlic oil Final Work Plan was placed into the docket on October 6, 2009. The Registration Review Proposed Final Decision was announced on April 30, 2010, and the comment period closed on June 9, 2010. No comments were received.

G. Water Quality

Garlic oil has not been identified as a cause of impairment for any water bodies listed as impaired under Section 303(d) of the Clean Water Act, based on information provided at: http://iaspub.epa.gov/tmdl_waters10/attains_nation.cy.cause_detail_303d?p_cause_group_id=885. In addition, no Total Maximum Daily Loads (TMDLs) have been developed for Garlic oil, based on information provided at: http://iaspub.epa.gov/tmdl_waters10/attains_nation.tmdl_pollutant_detail?p_pollutant_group_id=885&p_pollutant_group_name=PESTICIDES. More information on impaired water bodies and TMDLs can be found at <http://www.epa.gov/owow/tmdl/>. The Agency solicited comments when the Summary Document was issued in March 2009; however, no comments, data, or information regarding the existence of any water quality issues associated with Garlic oil were received.

H. Trade Irritants

Trade irritants are not expected for Garlic oil. Through the registration review process, the Agency is soliciting information on trade irritants and, to the extent feasible, will take steps toward facilitating irritant resolution. Growers and other stakeholders are asked to comment on any trade irritant issues resulting from lack of Maximum Residue Levels (MRLs) or disparities between U.S. tolerances or exemptions from tolerance and MRLs or exemptions from MRLs in key export markets, providing as much specificity as possible regarding the nature of the concern. Garlic oil has an exemption from the requirement of a tolerance to support their current use sites under 40 CFR § 180.1209, 40 CFR § 180.1243, 40 CFR § 180.1111, and 40 CFR § 180.1128, respectively. There are no U.S. tolerances for Garlic oil, nor are there Codex MRLs, so trade irritants are not expected for Garlic oil. The Agency did not receive any comments regarding the existence of any trade irritant issues associated with Garlic oil following issuance of the Summary Document.

I. Environmental Justice

EPA seeks to achieve environmental justice—the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income—in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency sought information, as explained in the Summary Document, on groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to registered pesticide products containing Garlic oil compared to the general population. The Agency did not receive any comments. At this time, EPA does not believe that use of the registered pesticide products containing Garlic oil will cause harm to or a disproportionate impact on at-risk communities.

For additional information regarding environmental justice issues, please visit EPA's website at: <http://www.epa.gov/compliance/environmentaljustice/index.html>.

III. FINAL REGISTRATION REVIEW DECISION

The Agency has determined that no additional data are required at this time to support registrations containing Garlic oil. The Agency has considered Garlic oil in light of the standard for registration and safety factors in FIFRA and FFDCA, as amended by FQPA. EPA has found that there are not likely to be any unreasonable adverse effects to the U.S. population in general, and to infants and children in particular, or to non-target organisms or the environment from the use of registered pesticide products containing Garlic oil when currently required label instructions are followed. In addition, EPA has made a "No Effect" determination for endangered and threatened species, and their designated critical habitat, for Garlic oil.

Therefore, in accordance with 40 CFR §§ 155.57 and 155.58, the Agency's final registration review decision is that the standards for Registration Review have been met and that the registrations of the 11 products containing Garlic oil may be maintained.

IV. NEXT STEPS AND TIMELINE

In accordance with 40 CFR § 155.58, the Agency is issuing this final decision document and placing it in the Garlic Oil registration review docket (EPA-HQ-OPP-0113). A Federal Register Notice will announce its availability.

V. BIBLIOGRAPHY

A. General References Supporting Registration Review of Garlic oil

1. EPA Reregistration Eligibility Document (RED) *Allium sativum* (Garlic). June 1992.
2. 40 CFR 158.2030.
3. Federal Register, May 24, 2002, Vol. 67 No 101 Pg.36537 Pesticides: tolerances in food, animal feeds, and raw agricultural commodities, Final Rule
4. Federal Register, May 17, 1995, Vol. 60 No. 96 Pg 26627 Pesticide Tolerances: Revision of Crop Groups; final Rule
5. Federal Register, December 7, 2007, Vol. 72 No. 235 Pg 69150 Pesticide Tolerance Crop Grouping Program, Final Rule
6. BPPD, 2009. Registration Review: product Chemistry Data Review for the Repellent Garlic Oil. Memo from J. Moore to C. Greene dated January 29, 2009.
7. BPPD, 2009. Summary of Ecotoxicity Data for Garlic Oil (*Allium sativum*) for the Registration Review Decision Document. Memo from M. Rexrode, PhD., to C. Greene dated January 31, 2009.
8. BPPD, 2009. Preliminary Human Health Assessment for the Registration Review of *Allium sativum* (Garlic). Memo from A. Gonzales to C. Greene dated January 29, 2009.
9. 21 CFR 582.10 and 21 CFR 582.20

B. Other References

List Studies Submitted to Support Registration of Products Containing Garlic oil

MRID	Citation Reference
146579	Sevana Co. (1984) [Product Chemistry of Sevana Bird Repellent Containing Red Pepper (Capsicum) and Garlic (Allium sativum)]. Un- published study. 42 p.
155079	Sevana Co. (1985) Agrigard Insect Repellent [Containing Red Pepper Extract, Garlic Extract and Polysorbate]. Unpublished study. 22 p.
40444400	Sevana Co. (1987) Submission of Efficacy and Product Chemistry Data for Agrigard Insect Repellent. Transmittal of 3 studies.
40444401	Querín, A. (1986) Letter sent to K. Yaralian dated Mar 3, 1986: "Efficacy Data: Agrigard Insect Repellent". Prepared by Sevana Co. 4 p.
40444402	Yaralian, K. (1987) Efficacy Data: Agrigard Insect Repellent. Unpublished study. 9 p.
40444403	Kalsec, Inc. Lab (1987) Product-specific Chemistry Data: Agrigard Insect Repellent. Unpublished study. 3 p.
41276500	Sevana Co. (1989) Submission of Efficacy Data To Support Registration of Sevana Dog and Cat Repellent. Transmittal of 6 studies.
41276501	Robinson, B. (1989) Efficacy Data: Sevana Dog and Cat Repellent. Unpublished study. 3 p.
41276502	Six, S. (1985) Efficacy Data: Sevana Dog and Cat Repellent. Un- published study. 3 p.
41276503	Yaralian, K. (1984) Efficacy Data: Sevana Dog and Cat Repellent. Unpublished study. 3 p.
41276504	Lawery, V. (1984) Efficacy Data: Sevana Dog and Cat Repellent. Un- published study. 3 p.
41276505	Mass, C. (1985) Efficacy Data: Sevana Dog and Cat Repellent. Unpublished study. 3 p.
41276506	Lawery, B. (1985) Efficacy Data: Sevana Dog and Cat Repellent. Un- published study. 3 p.
42448300	US EPA (1992) Submission of administrative record for Allium sativum in support of the reregistration standard (RED). Transmittal of 1 study.
42448301	US EPA (1992) Administrative Record for the Case 4007: Allium sativum: Reregistration Eligibility Document. Unpublished compilation. 643 p.
42699400	Plant Pro-Tec, Inc. (1993) Submission of product chemistry data in support of the registration for Plant Pro-Tec Garlic Devices. Transmittal of 1 study.
42699401	Walters, G. (1993) Allium sativum and Capsaicin in Plant Pro-Tec (Garlic) Devices: Lab Project Number: PP-T VOL 2. Unpublished study prepared by Plant Pro-Tec. 14 p.
42982700	E.I. duPont de Nemours and Co., Inc. (1993) Submission of Acute Toxicology Data of Alert Fungicide in Support of FIFRA 6(a)(2). Transmittal of 2 Studies.

MRID	Citation Reference
42982701	Clouzeau, J. (1993) Acute Dermal Irritation in Rabbits (with Alert Fungicide): Lab Project Number: 10379 TAL: N7872-201: 10379 TAL/N7872-201. Unpublished study prepared by Centre International de Toxicologie. 20 p.
42982702	Clouzeau, J. (1993) Acute Eye Irritation in Rabbits (with Alert Fungicide): Lab Project Number: 10333 TAL: N7872-201: 10333 TAL/N7872-201. Unpublished study prepared by Centre International de Toxicologie. 30 p.
42999800	Garlic Research Labs. (1993) Submission of product chemistry data in support of registration for 4007 Allium Sativum. Transmittal of 2 studies.
42999801	Brock, B. (1993) 4007 Allium Sativum 128827: Product Chemistry--Biochemical. Unpublished study prepared by Garlic Research Labs. 6 p.
42999802	Brock, B. (1993) 4007 Allium Sativum 128827: Product Chemistry--Biochemical: Lab Project Number: GB/3. Unpublished study prepared by Garlic Research Labs. 5 p.
43130700	American Biochemical Corp. (1994) Submittal of Primary Dermal and Eye Irritation Data in Support of Registration for Guardian Spray. Transmittal of 1 study.
43130701	Richotte, C. (1992) Primary Dermal and Eye Irritation Study in Albino Rabbits with Guardian Spray: Lab Project Number: X2B090G. Unpublished study prepared by Northview Pacific Laboratories, Inc. 17 p.
43153700	American Biochemical Corp. (1994) Submission of product chemistry data in support of registration of Guardian Spray. Transmittal of 1 study.
43153701	Zaletel, J. (1993) Physical and Chemical Characteristics of Garlic Water Insect Repellent: Lab Project Number: 35854/1. Unpublished study prepared by Zalco Lab., Inc. 26 p.
43268300	American Biochemical Corp. (1994) Submission of Product Chemistry Data for Guardian Spray & Guardian Spray Yard and Garden Insect Repellent in Support of Registration. Transmittal of 1 study.
43268301	McKenzie, J.; Etherton, J. (1994) Guardian Spray & Guardian Spray Yard and Garden Insect Repellent: Description of Beginning Materials and Manufacturing Process: Preliminary Analysis of Product Samples: Analytical Methods to Verify Certified Limits: Lab Project Number: GS-67450-AA. Unpublished study prepared by American Biochemical Corp. and Zalco Labs., Inc. 32 p.
43311400	Deer-Off, Inc. (1994) Submission of toxicity data in support of registration for Deer-Off Concentrate. Transmittal of 2 studies.
43311401	Wnorowski, G. (1994) Primary Eye Irritation (in the Rabbit): Deer-Off (Concentrate): Lab Project Number: 3167. Unpublished study prepared by Product Safety Labs. 21 p.
43311402	Wnorowski, G. (1994) Primary Skin Irritation (in the Rabbit): Deer-Off (Concentrate): Lab Project Number: 3168. Unpublished study prepared by Product Safety Labs. 16 p.
43396600	DEER-OFF, Inc. (1994) Submission of product chemistry data in support of registration of

MRID	Citation Reference
	DEER-OFF Concentrate. Transmittal of 3 studies.
43396601	Loucas, A. (1994) DEER-OFF Concentrate: Product Identity and Disclosure of Ingredients. Unpublished study prepared by DEER-OFF, Inc. 3 p.
43396602	Loucas, A. (1994) DEER-OFF Concentrate: Description of Beginning Materials and Manufacturing Process. Unpublished study prepared by DEER-OFF, Inc. 7 p.
43396603	Loucas, A. (1994) DEER-OFF Concentrate: Discussion of the Formation of Impurities. Unpublished study prepared by DEER-OFF, Inc. 3 p.
43436000	Deer-Off (1994) Submission of Product Chemistry Data in Support of Application for Registration of DEER-OFF. Transmittal of 3 Studies.
43436001	Loucas, A. (1994) DEER-OFF: Product Identity and Disclosure of Ingredients. Unpublished study prepared by Deer-Off. 3 p.
43436002	Loucas, A. (1994) DEER-OFF: Description of Beginning Materials and Manufacturing Process. Unpublished study prepared by Deer-Off. 7 p.
43436003	Loucas, A. (1994) DEER-OFF: Discussion of the Formation of Impurities. Unpublished study prepared by Deer-Off. 3 p.
43482800	Garlic Research Labs (1994) Submission of Product Chemistry Data in Support of Registration of Allium sativum. Transmittal of 3 Studies.
43482801	Anderson, W. (1994) Product Chemistry--Biochemical: (4007 Allium Sativum 128827): Product Identity: Manufacturing Process: Discussion of Formation of Unintentional Ingredients. Unpublished study prepared by Garlic Research Labs. 6 p.
43482802	Anderson, W. (1994) Product Chemistry--Biochemical: (4007 Allium Sativum 128827): Certification of Limits: Analytical Methods: Lab Project Number: GB-3. Unpublished study prepared by Garlic Research Labs. 5 p.
43482803	Anderson, W. (1994) Product Chemistry--Biochemical: (4007 Allium Sativum 128827): Physical State: Density: pH: Lab Project Number: GB-4. Unpublished study prepared by Garlic Research Labs. 7 p.
43714700	Cal Crop USA L.L.C. (1995) Submission of Product Chemistry Data in Support of the Registration of Cal Crop USA Envirepel. Transmittal of 1 Study.
43714701	Davis, K. (1995) Product Chemistry Data of Cal Crop USA Envirepel: Lab Project Numbers: RPCD: 76757. Unpublished study prepared by RegWest Co. 14 p.
43766600	Cal Crop USA L.L.C. (1995) Submission of Product Chemistry Data in Support of the Registration of Cal Crop USA Envirepel. Transmittal of 1 Study.
43766601	Davis, K. (1995) Product Chemistry Data of Cal Crop USA Envirepel: Lab Project Number: RPCD. Unpublished study prepared by RegWest Co. 14 p.
43951300	Garlic Research Labs (1995) Submission of Product Chemistry and Efficacy Data in

MRID

Citation Reference

- Support of the Application for Registration of Mosquito Barrier. Transmittal of 4 Studies.
- 43951301 Brock, B. (1995) Allium Sativum--Product Chemistry--Biochemical: Product Identity, Manufacturing Process, Discussion of Formation of Unintentional Ingredients. Unpublished study prepared by Garlic Research Labs. 6 p.
- 43951302 Brock, B. (1995) Allium sativum--Product Chemistry--Biochemical: Certification of Limits, Analytical Methods. Unpublished study prepared by Garlic Research Labs. 5 p.
- 43951303 Brock, B. (1995) Allium sativum--Product Chemistry--Biochemical: Physical State, Density, pH. Unpublished study prepared by Garlic Research Labs. 7 p.
- 43951304 Brock, B. (1995) Allium sativum--Efficacy Data--Repelling Mosquitoes. Unpublished study prepared by Garlic Research Labs. 22 p.
- 43951600 Garlic Research Labs (1995) Submission of Product Chemistry and Efficacy Data in Support of the Application for Registration of Allium Sativum. Transmittal of 4 Studies.
- 43951601 Brock, B. (1995) Allium sativum--Product Chemistry--Biochemical: Product Identity, Manufacturing Process, Discussion of Formation of Unintentional Ingredients. Unpublished study prepared by Garlic Research Labs. 6 p.
- 43951602 Brock, B. (1995) Allium sativum--Product Chemistry--Biochemical: Certification of Limits, Analytical Methods. Unpublished study prepared by Garlic Research Labs. 5 p.
- 43951603 Brock, B. (1995) Allium sativum--Product Chemistry--Biochemical: Physical State, Density, pH. Unpublished study prepared by Garlic Research Labs. 7 p.
- 43951604 Brock, B. (1995) Allium sativum--Efficacy Data--Repelling Mosquitoes. Unpublished study prepared by Garlic Research Labs. 22 p.
- 43980800 Garlic Research Labs (1996) Submission of Product Chemistry Data in Support of Registration of the Biochemical Garlic. Transmittal of 3 Studies.
- 43980801 Brock, B. (1995) Allium sativum--Product Chemistry--Biochemical: Product Identity, Manufacturing Process, and Discussion of Formation of Unintentional Ingredients. Unpublished study prepared by Garlic Research Labs. 6 p.
- 43980802 Brock, B. (1995) Allium sativum--Product Chemistry--Biochemical: Certification of Limits, Analytical Methods. Unpublished study prepared by Garlic Research Labs. 5 p.
- 43980803 Brock, B. (1995) Allium sativum--Product Chemistry--Biochemical: Physical State, Density, and pH. Unpublished study prepared by Garlic Research Labs. 7 p.
- 44246500 Cal Crop USA L.L.C. (1997) Submission of Product Chemistry Data in Support of the Application for Registration for Cal Crop USA Nutripel. Transmittal of 1 Study.
- 44246501 Davis, K. (1997) Product Chemistry Data of Cal Crop USA Nutripel: Lab Project Number: EPCD. Unpublished study prepared by RegWest Co. 13 p.
- 44316200 Cal Crop USA L.L.C. (1997) Submission of Toxicity Data in Support of the Amended

MRID	Citation Reference
	Registration for Cal Crop USA Envirepel. Transmittal of 2 Studies.
44316201	Robbins, G. (1997) Primary Eye Irritation Study (in Rabbits) of Cal Crop USA Envirepel: Lab Project Number: D3503. Unpublished study prepared by Cosmopolitan Safety Evaluation, Inc. 22 p.
44316202	Robbins, G. (1997) Primary Dermal Irritation Study (in Rabbits) of Cal Crop USA Envirepel: Lab Project Number: E3503. Unpublished study prepared by Cosmopolitan Safety Evaluation, Inc. 18 p.
44603300	Cal Crop USA, LLC (1998) Submission of Product Chemistry and Toxicity Data in Support of the Application for Registration of Envirepel 20. Transmittal of 4 Studies.
44603301	Davis, K. (1998) Product Chemistry of Envirepel-20: Lab Project Number: PCD 68826-G. Unpublished study prepared by RegWest Company. 14 p.
44603302	Klausner, K. (1998) Physical and Chemical Characteristics of Envirepel-20: Lab Project Number: 98G-0753: REG/PCHEM/007-97/000. Unpublished study prepared by Toxikon Corporation. 26 p.
44603303	Robbins, G. (1997) Primary Eye Irritation Study of Cal Crop USA Envirepel 40% Concentrate (in Rabbits): Lab Project Number: D3504. Unpublished study prepared by Cosmopolitan Safety Evaluation, Inc. 23 p.
44603304	Robbins, G. (1997) Primary Dermal Irritation Study of Cal Crop USA Envirepel 40% Concentrate (in Rabbits): Lab Project Number: E3504. Unpublished study prepared by Cosmopolitan Safety Evaluation, Inc. 18 p.
44638600	Cal Crop USA LLC (1998) Submission of Product Chemistry Data in Support of the Application for Registration of Nutripel-20. Transmittal of 1 Study.
44638601	Davis, K. (1998) Product Chemistry Data of Nutripel-20: Lab Project Number: PCD 68826-U. Unpublished study prepared by RegWest Company. 12 p.
44698500	Kitten Fertilizer & Supply, Inc. (1998) Submission of Environmental Fate and Efficacy Data in Support of the Application for Registration of Aphid-Pruf. Transmittal of 2 Studies.
44698501	Sikes, J. (1998) Further Studies on Aphid Control in Cotton: (Aphid-Pruf). Unpublished study prepared by SCAN, Inc. 24 p.
44698502	Sikes, J. (1993) Movement of Sugars in Plant Leaves as Influenced by the Application of Foli-Zyme, Sett and Charge It. Unpublished study prepared by SCAN, Inc. 40 p.
44968900	Helena Chemical Company (1999) Submission of Product Chemistry Data in Support of the Registration of Allityn. Transmittal of 2 Studies.
44968901	Volgas, G. (1999) Manufacturing Process for Allityn: Lab Project Number: 5905-AL-12. Unpublished study prepared by Helena Chemical Company. 11 p. {OPPTS 880.1200}
44968902	Smith, J. (1999) Analytical Method for Allityn: Lab Project Number: 5905-AL-19. Unpublished study prepared by Helena Chemical Company. 12 p. {OPPTS 880.1700}

MRID	Citation Reference
45859500	Holy Terra Products, Inc. (2003) Submission of Product Chemistry and Toxicity Data in Support of the Application for Registration of Anti-Pest-O. Transmittal of 1 Study.
45859501	White, J. (2003) Data Submission for Anti-Pest-O: Biochemical Pesticide Registration Application: Lab Project Number: 60658. Unpublished study prepared by Holy Terra Products, Inc. 183 p.
46032700	Woodstream Corporation (2003) Submission of Product Chemistry and Toxicity Data in Support of the Application for Registration of WS-DOSPCON X02. Transmittal of 1 Study.
46032701	Ehresman, N. (2003) WS-Dospcon X02: Product Identity and Composition, Beginning Materials, Production Process and Formation of Impurities. Project Number: WS/DOSPCON/X02/001. Unpublished study prepared by Woodstream Corporation. 64 p.
46032702	Ehresman, N. (2003) WS-Dospcon X02: Analysis and Certification of Product Ingredients, Certification of Limits, Analytical Method to Verify Certified Limits. Project Number: WS/DOSPCON/X02/002. Unpublished study prepared by Woodstream Corporation. 7 p.
46032704	Ehresman, N. (2003) WS-Dospcon X02: Physical and Chemical Properties. Project Number: WS/DOSPCON/X02/003. Unpublished study prepared by Woodstream Corporation. 7 p.
46032705	Sinning, D. (2003) Physical and Chemical Characteristics of WS-DOSPCON X02: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity and Relative Density. Project Number: 2720/09. Unpublished study prepared by Case Consulting Laboratories, Inc. 7 p.
46032706	Merkel, D. (2003) Acute Oral Toxicity Up and Down Procedure in Rats: WS-DOSPCON X02. Project Number: 13517, P320/UDP. Unpublished study prepared by Product Safety Labs, Food Products Laboratory, Silliker Laboratories of New Jersey, Inc. 15 p.
46032707	Merkel, D. (2003) Acute Dermal Toxicity Study in Rats - Limit Test: WS-DOSPCON X02. Project Number: 13518, P322. Unpublished study prepared by Product Safety Labs, Food Products Lab, Sillker Labs. 15 p.
46032708	Merkel, D. (2003) Acute Inhalation Toxicity Study in Rats - Limit Test: WS-DOSPCON X02. Project Number: 13519, WS/DOSPCON/X02. Unpublished study prepared by Product Safety Labs, Food Products Laboratory, and Silliker Laboratories. 22 p.
46032709	Merkel, D. (2003) Primary Eye Irritation Study in Rabbits: WS-DOSPCON X02. Project Number: 13520, P324. Unpublished study prepared by Product Safety Labs. 16 p.
46032710	Merkel, D. (2003) Primary Skin Irritation Study in Rabbits. Project Number: 13520, P324. Unpublished study prepared by Product Safety Labs. 16 p.
46032711	Merkel, D. (2003) Dermal Sensitization Study in Guinea Pigs (Buehler Method). Project Number: 13522, P328. Unpublished study prepared by Product Safety Labs, Food Products Laboratory, Silliker Laboratories of New Jersey, Inc. 28 p.
46061600	Holy Terra Products, Inc. (2003) Submission of Product Chemistry and Toxicity Data in

MRID

Citation Reference

Support of the Applications for Registration of Anti-Pest-O Concentrate, Anti-Pest-O MUP, and Anti-Pest-O RTU. Transmittal of 6 Studies.

- 46061601 White, J.; Cambridge, N. (2003) Product Identity and Composition, Certification of Ingredient Limits, and Discussion of Impurities of Anti-Pest-O Original Concentrate (Including Anti-Pest-O-MUP) and Ready to Use. Project Number: ANTI/PEST/O/03/03, WD00750/000/A0T0/0803/0001. Unpublished study prepared by Exponent. 28 p.
- 46061602 White, J.; Cambridge, N. (2003) Description of Materials Used to Produce the Product, Description of Production Process, and Description of Formulation Process: (Anti-Pest-O Concentrate, Anti-Pest-O MUP, and Anti-Pest-O RTU). Project Number: ANTI/PEST/O/03/04, WD00750/000/A0T0/0803/0002. Unpublished study prepared by Exponent. 36 p.
- 46061603 Kuhn, J. (2003) Acute Oral Toxicity Study (UDP) in Rats: Anti-Pest-O: Final Report. Project Number: 7592/03. Unpublished study prepared by Stillmeadow, Inc. 10 p.
- 46061604 Kuhn, J. (2003) Acute Dermal Toxicity Study in Rabbits: Anti-Pest-O: Final Report. Project Number: 7593/03. Unpublished study prepared by Stillmeadow, Inc. 12 p.
- 46061605 Kuhn, J. (2003) Acute Eye Irritation Study in Rabbits: Anti-Pest-O: Final Report. Project Number: 7594/03. Unpublished study prepared by Stillmeadow, Inc. 16 p.
- 46061607 Huntley, K.; Koch, D. (2003) Determination of Color, Physical State, Odor, Density, pH, Viscosity, and Preliminary Analysis for ANTI-PEST-O (Ready to Use) and ANTI-PEST-O (Concentrate). Project Number: 48266. Unpublished study prepared by Analytical Bio-Chemistry Labs., Inc. 82 p.
- 46071000 Woodstream Corp. (2003) Submission of Product Chemistry Data in Support of the Application for Registration of WS-DOSP X03. Transmittal of 4 Studies.
- 46071001 Ehresman, N. (2003) WS-DOSP X03: Product Identity and Composition, Beginning Materials, Production Process and Formation of Impurities. Project Number: WS/DOSP/X03/001. Unpublished study prepared by Woodstream Corp. 38 p.
- 46071002 Ehresman, N. (2003) WS-DOSP X03: Analysis and Certification of Product Ingredients, Certification of Limits, Analytical Method to Verify Certified Limits. Project Number: WS/DOSP/X03/002. Unpublished study prepared by Woodstream Corp. 13 p.
- 46071003 Ehersman, N. (2003) WS-DOSP X03: Physical and Chemical Properties. Project Number: WS/DOSP/X03/003. Unpublished study prepared by Woodstream Corp. 6 p.
- 46071004 Sinning, D. (2003) Physical and Chemical Characteristics of WS-DOSP X03: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity and Relative Density. Project Number: 2720/10. Unpublished study prepared by Case Consulting Laboratories, Inc. 7 p.
- 46084200 Holy Terra Products, Inc. (2003) Submission of Toxicity Data in Support the Application for Registration of Anti-Pest-O Concentrate. Transmittal of 1 Study.

MRID	Citation Reference
46084201	Kuhn, J. (2003) Acute Dermal Irritation Study in Rabbits: Anti-Pest-O: Final Report. Project Number: 7595/03. Unpublished study prepared by Stillmeadow, Inc. 10 p.
46399000	Woodstream Corporation (2004) Submission of Product Chemistry Data in Support of the Application for Registration of Deer-Off Concentrate II. Transmittal of 3 Studies.
46399001	Ehresman, N. (2004) Product Chemistry for Deer-Off Concentrate II. Unpublished study prepared by Woodstream Corporation. 64 p.
46399002	Sinning, D. (2004) Deer Off Concentrate II: Preliminary Analysis and Enforcement Analytical Method. Project Number: 2720/45. Unpublished study prepared by Case Consulting Laboratories, Inc. 13 p.
46399003	Sinning, D. (2004) Physical and Chemical Characteristics of Deer Off Concentrate II: Color, Physical State, Odor, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity and Relative Density. Project Number: 2720/46. Unpublished study prepared by Case Consulting Laboratories, Inc. 8 p.
46399100	Woodstream Corporation (2004) Submission of Product Chemistry Data in Support of the Application for Registration of Deer-Off RTU II. Transmittal of 2 Studies.
46399101	Ehresman, N. (2004) Product Chemistry for Deer-Off RTU II. Unpublished study prepared by Woodstream Corporation. 47 p.
46399102	Sinning, D. (2004) Physical and Chemical Characteristics of Deer Off RTU II: Color, Physical State, Odor, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity and Relative Density. Project Number: 2720/47. Unpublished study prepared by Case Consulting Laboratories, Inc. 8 p.
46675600	Woodstream Corp. (2005) Submission of Product Chemistry Data in Support of the Application for Registration of Deer-Off Concentrate II. Transmittal of 1 Study.
46675601	Ehresman, N. (2005) Supplemental Product Chemistry for Deer-Off Concentrate II. Unpublished study prepared by Woodstream Corp. 9 p.
46675700	Woodstream Corp. (2005) Submission of Product Chemistry Data in Support of the Application for Registration of Deer-Off RTU II. Transmittal of 1 Study.
46675701	Ehresman, N. (2005) Supplemental Product Chemistry for Deer-Off RTU II. Unpublished study prepared by Woodstream Corp. 9 p.
46675800	Woodstream Corp. (2005) Submission of Product Chemistry Data in Support of the Application for Registration of WS-DOSPCON X02. Transmittal of 2 Studies.
46675801	Sinning, D. (2004) Physical and Chemical Characteristics of WS-DOSPCON X02: Odor. Project Number: 2720/57. Unpublished study prepared by Case Consulting Laboratories, Inc. 6 p.
46675802	Ehresman, N. (2005) Supplemental Product Chemistry for WS-DOSPCON X02. Unpublished study prepared by Woodstream Corp. 9 p.

MRID	Citation Reference
46676000	Woodstream Corp. (2005) Submission of Product Chemistry Data in Support of the Application for Registration of WS-DOSP X03. Transmittal of 2 Studies.
46676001	Sinning, D. (2004) Physical and Chemical Characteristics of WS-DOSP X03: Odor. Project Number: 2720/58. Unpublished study prepared by Case Consulting Laboratories, Inc. 6 p.
46676002	Ehresman, N. (2005) Supplemental Product Chemistry for WS-DOSP X03. Unpublished study prepared by Woodstream Corporation. 9 p.
46874100	Woodstream Corporation (2006) Submission of Product Chemistry Data in Support of the Registration of Deer-Off Concentrate II. Transmittal of 1 Study.
46874101	Sinning, D. (2006) Physical Chemical Characteristics of Deer Off Concentrate II: Storage Stability. Project Number: 2720/59. Unpublished study prepared by Case Consulting Laboratories, Inc. 13 p.
47223300	Balk Family Trust (2007) Submission of Toxicity and Product Chemistry Data in Support of the Application for Registration of Scoot Deer and Rabbit Repellent. Transmittal of 4 Studies.
47223301	Balk, R. (2007) Product Chemistry, Product Identity, Starting Material and Manufacturing Process, Preliminary Analysis, and Certification Limits for Scoot Deer and Rabbit Repellent. Unpublished study prepared by Balk Family Trust. 25 p.
47223302	Balk, R. (2007) Chemical and Physical Properties for Scoot Deer and Rabbit Repellent. Unpublished study prepared by Balk Family Trust. 12 p.
47223303	Balk, R. (2007) Acute Mammalian Toxicity for Scoot Deer and Rabbit Repellent . Unpublished study prepared by Balk Family Trust. 12 p.
47223304	Balk, R. (2007) Acute Ecological Toxicity for Scoot Deer and Rabbit Repellent. Unpublished study prepared by Balk Family Trust. 13 p.
47354600	Balk Family Trust (2008) Submission of Product Chemistry and Toxicity Data in Support of the Application for Registration of Scoot Deer and Rabbit Repellent. Transmittal of 4 Studies.
47354601	Balk, R. (2008) Product Chemistry, Product Identity, Starting Material and Manufacturing Process, Preliminary Analysis, and Certification Limits for Scoot Deer and Rabbit Repellent. Project Number: PL/00101, 050401, 134/05. Unpublished study prepared by Balk Family Trust. 60 p.
47354602	Balk, R. (2008) Chemical and Physical Properties for Scoot Deer and Rabbit Repellent. Unpublished study prepared by Balk Family Trust. 11 p.
47354603	Balk, R. (2008) Acute Mammalian Toxicity for Scoot Deer and Rabbit Repellent. Unpublished study prepared by Balk Family Trust. 13 p.
47354604	Balk, R. (2008) Acute Ecological Toxicity for Scoot Deer and Rabbit Repellent. Project Number: 134/05. Unpublished study prepared by Balk Family Trust. 9 p.

MRID	Citation Reference
47357600	Woodstream Corporation (2008) Submission of Product Chemistry Data in Support of the Application for Registration of Deer Off RTU III. Transmittal of 3 Studies.
47357601	Mateer, C. (2008) Deer-Off RTU III: Product Identity and Composition, Beginning Materials, Production Process and Formation of Impurities. Project Number: WS/DEEROFFRTUIII/001. Unpublished study prepared by Woodstream Corporation. 46 p.
47357602	Mateer, C. (2008) Deer-Off RTU III: Analysis and Certification of Product Ingredients, Certification of Limits, Analytical Method to Verify Certified Limits. Project Number: WS/DEEROFFRTUIII/002. Unpublished study prepared by Woodstream Corporation. 13 p.
47357603	Sinning, D. (2007) Physical and Chemical Characteristics of Deer Off III Ready to Use: Color, Physical State, Odor, Oxidation/Reduction, pH, Viscosity and Relative Density. Project Number: 2720/131. Unpublished study prepared by Case Consulting Laboratories, Inc. 11 p.
47357700	Woodstream Corporation (2008) Submission of Product Chemistry and Toxicity Data in Support of the Application for Registration of Deer Off Concentrate III. Transmittal of 12 Studies.
47357701	Mateer, C. (2008) Deer-Off Concentrate III: Product Identity Composition, Beginning Materials, Production Process and Formation of Impurities. Unpublished study prepared by Woodstream Corporation. 66 p.
47357702	Mateer, C. (2008) Deer-Off Concentrate III: Analysis and Certification of Product Ingredients, Certification of Limits, Analytical Method to Verify Certified Limits. Unpublished study prepared by Woodstream Corporation. 13 p.
47357703	Sinning, D. (2008) Deer Off III Concentrate: Preliminary Analysis. Project Number: 2720/139. Unpublished study prepared by Case Consulting Laboratories, Inc. 11 p.
47357704	Sinning, D. (2007) Physical and Chemical Characteristics of Deer Off III Concentrate: Color, Physical State, Odor, Oxidation/Reduction, pH, Viscosity and Relative Density. Project Number: 2720/132, 060407C. Unpublished study prepared by Case Consulting Laboratories, Inc. 11 p.
47357705	Nitka, S. (2007) Acute Oral Toxicity in Rats: (Deer Off III Concentrate): Limit Test. Project Number: T07/2779/3, 060407C. Unpublished study prepared by Consumer Product Testing Laboratory. 12 p.
47357706	Nitka, S. (2007) Acute Dermal Toxicity in Rabbits: Deer Off III Concentrate: Limit Test. Project Number: T07/2779/4, 060407C. Unpublished study prepared by Consumer Product Testing Laboratory. 13 p.
47357707	Nitka, S. (2007) Acute Inhalation Toxicity in Rats: Deer-Off III Concentrate: Limit Test. Project Number: T07/2779/5, 060407C. Unpublished study prepared by Consumer Product Testing Laboratory. 15 p.

MRID

Citation Reference

- 47357708 McCombie, W. (2008) Discussion of Acute Inhalation Toxicology Data:(Deer-Off III Concentrate). Unpublished study prepared by Woodstream Corporation. 5 p.
- 47357709 Nitka, S. (2007) Acute Eye Irritation in Rabbits: Deer Off III Concentrate. Project Number: T07/2779/2, 060407C. Unpublished study prepared by Consumer Product Testing Laboratory. 14 p.
- 47357710 Nitka, S. (2007) Acute Dermal Irritation in Rabbits: Deer Off III Concentrate. Project Number: T07/2779/1, 060407C. Unpublished study prepared by Consumer Product Testing Laboratory. 13 p.
- 47357711 Nitka, S. (2007) Guinea Pig Sensitization: Deer Off III Concentrate. Project Number: T07/2779/6, 060407C. Unpublished study prepared by Consumer Product Testing Laboratory. 21 p.
- 47357712 Nitka, S. (2007) Guinea Pig Sensitization: Deer Off III Concentrate. Project Number: T07/2779/7. Unpublished study prepared by Consumer Product Testing Laboratory. 21 p.

VI. GLOSSARY OF ACRONYMS AND ABBREVIATIONS

APHIS	Animal and Plant Health Inspection Service
BPPD	Biopesticides and Pollution Prevention Division
BRADs	Biopesticides Registration Action Documents
°C	degrees Celsius
CFR	Code of Federal Regulations
cfu	colony-forming unit
cm	centimeter
EC ₅₀	half maximal effective concentration
EDSP	Endocrine Disruptor Screening Program
EEC	estimated environmental concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EPA	Environmental Protection Agency (the Agency)
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act
FR	Federal Register
g	grams
g/kg	grams per kilogram
kg	kilograms
L	liter
LC ₅₀	median lethal concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air, or feed (e.g., mg/L, mg/kg, or ppm).
LD ₅₀	median lethal dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal (e.g., mg/kg).
LOC	level of concern
LOEC	lowest observable effect concentration
mg	milligrams
mg/kg	milligrams per kilogram
mg/L	milligrams per liter
mL	milliliter
mL/kg	milliliters per kilogram
MRID Nos.	Master Record Identification Numbers
NOAEC	no observable adverse effect concentration
NOEC	no observable effect concentration
OECD	Organization for Economic Cooperation and Development
OPP	Office of Pesticide Programs
OPPTS	Office of Prevention, Pesticides, and Toxic Substances
PC Code	Pesticide Chemical Code
ppm	parts per million
PWP	preliminary work plan
SAR	systemic acquired resistance
TGAI	technical grade of the active ingredient
TMDLs	Total Maximum Daily Loads
TSA	trypticase soy agar
USDA	United States Department of Agriculture

VII. APPENDIX

TABLE 1 Garlic oil Chemical Identity

Common Name	Garlic, Garlic oil, Garlic Juice, Garlic Water
Chemical Name	Extract of <i>Allium sativum</i>
IUPAC	N/A
Trade Names	N/A
Molecular Weight	varies
PC Code	128827
CAS Registry Number	8000-78-0
Empirical Formula	N/A
Registration Review	4007
Case Number	
Chemical Structure	N/A

Table 2 Product Chemistry Data Requirements Summary

Guideline No.	Physical and Chemical Properties	Status	Value
830.1100	Product Identity and Composition	A	Refer to Table 1.
830.1200	Description of starting materials, production and formulation process	A	CBI
830.1400	Discussion of formation of impurities	A	CBI
830.1700	Preliminary analysis	A	CBI (EP)
830.6302	Color	A	Light tan to dark green
830.6303	Physical state	A	Liquid or powder
830.6304	Odor	A	Strong Garlic
830.6313	Stability to normal and elevated temperatures, metals and metal ions	A	Stable
830.7000	pH	A	5.5-6.0
830.7220	Boiling point/boiling range	N/A	Testing done on EP
830.7300	Density	N/A	Testing done on EP
830.7520	Particle size, fiber length, and diameter distribution	N/A	Testing done on EP

TABLE 3 Registered Products Containing Garlic oil

Registration #	Registration Name	Current Status	% of Active Ingredient
<u>5905-531</u>	ALLITYN INSECT REPELLENT	<u>Active - Registered (08-Dec-1998)</u>	50
<u>44688-1</u>	APHID-PRUF	<u>Active - Registered (05-Jun-2000)</u>	10.8
<u>65615-7</u>	SCOOT DEER & RABBIT REPELLENT	<u>Active - Registered (18-Apr-2008)</u>	.12
<u>67356-1</u>	DEER-OFF DEER REPELLENT CONCENTRATE	<u>Active - Registered (27-Apr-1995)</u>	.005
<u>67356-2</u>	DEER-OFF DEER REPELLENT SPRAY	<u>Active - Registered (23-May-1995)</u>	.0006
<u>67356-3</u>	WS-DOSPCON X02	<u>Active - Registered (28-Dec-2005)</u>	.05
<u>67356-4</u>	WS-DOSP X03	<u>Active - Registered (28-Dec-2005)</u>	.0063
<u>67356-5</u>	DEER-OFF RTU II	<u>Active - Registered (28-Dec-2005)</u>	.0063
<u>67356-6</u>	DEER-OFF CONCENTRATE II	<u>Active - Registered (28-Dec-2005)</u>	.05
<u>67356-7</u>	DEER OFF RTU III	<u>Active - Conditionally Registered (12-Sep-2008)</u>	.001
<u>67356-8</u>	DEER OFF CONCENTRATE III	<u>Active - Conditionally Registered (12-Sep-2008)</u>	.007

